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USDOC FOR 3131/USFCS/OIO/ANESA/KREISSL
USDOC FOR 4530/MAC/ANESA/OSA
ICE HQ FOR STRATEGIC INVESTIGATIONS
STATE FOR EB/ESP

E.O. 12958: N/A

TAGS: [ETTC](#) [ETRD](#) [BEXP](#) [IN](#)

SUBJECT: EXTRANCHECK: POST-SHIPMENT VERIFICATION: ARCH PHARMALABS
LTD., HYDERABAD, LICENSE NO. D349966

REF: USDOC 03130

1. Unauthorized disclosure of the information provided below is prohibited by Section 12(c) of the Export Administration Act.

2. Export Control Officer (ECO) Paul Cushman, Former ECO Michael Rufe and BIS FSN Narayan conducted a Post-shipment Verification (PSV) at Arch Pharmalabs Limited (Arch), Medak District, Andhra Pradesh, approximately 70 kilometers north of Hyderabad, on April 18, 2007.

2. BIS requested a PSV at Arch, a private sector company, located at Survey No. 323, Gundlamachnur Village, Hathnoora Mandal, Medak District, Andhra Pradesh, Tel: 91-8455-233993, Fax: 91-8455-233542, email: krishnadas@archgroupinindia.com, website: www.archpharmalabs.com. Arch was listed as the Ultimate Consignee; Shanbhag and Associates (Shanbhag), Mumbai, as the Intermediate Consignee; and Lutz-Pumpen GmbH, Germany as the Foreign Purchaser, for two Model 5701-080 half-inch Air operated double diaphragm pump controlled under ECCN 2B350. The license applicant was Lutz-Jesco (Lutz-Jesco) America Corp., Rochester, NY.

3. The BIS Team met with K.V. Subba Raju (Raju), Assistant General Manager - Maintenance, Arch.

4. Former ECO Rufe along with BIS FSN Narayan conducted a favorable PLC for one similar Lutz-Jesco pump under a different BIS export license D354363. Raju provided a copy of Shanbhag Tax Invoice, Arch Purchase Order, Arch End-use statement and Shanbhag Delivery Receipt/Challan confirming receipt of one pump at Arch. Arch issued a purchase order in favor of Shanbhag for three pumps. An Arch condition stated that after the first pump's satisfactory performance, it would only then purchase the other two pumps. Shanbhag's Tax Invoice and Delivery Receipt confirm that Arch purchased only one pump. Raju cited the reason for canceling the order for the other two pumps as the unusual delay in delivering the first pump. He stated that Arch issued the purchase order on September 10, 2005 and Shanbhag delivered the pump on July 13, 2006. This delay forced Arch to use locally-made pumps. He stated that although Arch prefers to use Lutz-Jesco pumps, such delivery timeframe is unacceptable. Therefore, for the time-being, Arch will continue to use locally-made pumps.

5. Raju confirmed that this is the only Lutz-Jesco pump that Arch purchased from Shanbhag for which he produced documentation that completely matches documentation provided during a PLC at Arch for license D354363. BIS is requested to contact Lutz-Jesco to ascertain the number of pumps shipped to Arch and to rectify the discrepancy for issuance of two BIS export licenses D354363 and D349966 for the same commodity.

¶6. Raju stated that nearly a month ago, the pump became faulty and was removed from the plant. The pump was lying in the administrative office of Arch. BIS Team noted the part no. as 5701-080 and serial no. as 127238. The part and serial numbers match those found on the Shanbhag Delivery Receipt.

¶7. The Lutz-Jesco pump has been replaced with a locally-manufactured pump. It will be kept as stand-by after it is repaired. Raju stated that the pump is used for unloading and transferring of liquids from tanks/drums during the manufacture of bulk active pharmaceutical ingredients (API). The air-operated pump is mainly used to transfer isoxazoles with other liquids into the reactor and subsequently to various processes for formulations to produce semi-synthetic penicillin. It will also be used to manufacture clopidogrel bisulphate, an antiplatelet drug. BIS Team was given a tour of Block No. 3 of Arch's plant and was shown the site where the air-operated pump operated before becoming faulty. The Arch facility is run in three shifts and guarded 24 hours a day.

¶6. Established in 1994, Arch is a bulk API and intermediate pharmaceuticals manufacturing company. Arch is the leading manufacturer of isoxazole penicillin side chains, and maintains a product portfolio that supports numerous therapeutic segments including antibiotics, psychotropics, cardiovascular, antiulcerants, antihistamines and antifungals. Arch exports 60 percent of its volume to Italy, Germany, Barcelona, Netherlands, Mexico, Egypt, Oman, Pakistan and Bangladesh and the remaining 40 percent is sold domestically. Arch has five manufacturing facilities including three in Maharashtra, one in Andhra Pradesh, and one in Gurgaon, Haryana. Arch has a subsidiary in the U.S. based in Sonoma, CA. Arch employs approximately 650 personnel at all five Indian locations. Arch reported total revenues of \$36 million in fiscal year 2004-05.

¶7. Recommendation: Post recommends Arch Pharmalabs Limited as a reliable recipient of the controlled U.S. origin commodity. All indications are that the listed commodity is used in accordance with U.S. export control regulations. (PSCUSHMAN/PNARAYAN) Pyatt